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HM12/0517

EXAMINER

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ALEXANDRIA VA 22314-1176

KISHORE, G  
ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/17/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2-20-01 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

Part II SUMMARY OF ACTION

- ☒ Claims 39-61 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
- ☐ Claims \_\_\_\_\_ have been cancelled.
- ☐ Claims \_\_\_\_\_ are allowed.
- ☒ Claims 39-61 are rejected.
- ☐ Claims \_\_\_\_\_ are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

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### DETAILED ACTION

The filing under 1.53 (d) and the preliminary amendment dated 2-20-01 are acknowledged.

Claims included in the prosecution are 39-61.

#### *Claim Rejections - 35 U.S.C. § 112*

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 39-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what applicants intend to convey by '----and where the acyl chains may contain one or more unsaturated bonds together with one or more substances selected from the group consisting of ----' on lines 7-10 of claim 39. First of all, 'selected from the group consisting of' is not a proper expression since there is only one Markush member (b). Secondly, R3 has already an acyl chain which has 6-24 carbon atoms and does the expression mean that additional fatty acids with 6-24 carbon atoms is bonded to the already existing carbon chain? The expression is confusing. Furthermore, 'may contain' is not a positive recitation (two places in claim 39 and also in dependent claims). Also unclear

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what 'a)' and 'b0' in 'wherein the percentage of monoglyceride a) in fatty acid b0' represents (also in claim 54).

'an antigen or vaccine that is selected from the group consisting of antigens and vaccines relevant to humans and animals' in claim 46 is confusing. First of all, the Markush expression is improper since the same expression is recited twice. It also implies that claim 1 antigens and vaccines are not relevant to humans and animals. What is a relevant in this context? (also in claim 54)

Proper Markush format 'selected from the group consisting of' should be followed in claim 48. The term either 'and' OR 'or' should only be used before the last Markush component. The difference between surfactants and organic solvents is unclear. Surfactants are solvents. What is a hydrophobic agent as used in the context in this claim? An organic solvent is a hydrophobic agent.

Claim 50 is not further limiting claim 39 in that the parent claim already has the parenteral and mucosal limitations.

Claim 53 recites 90 grams of antigen or vaccine component. Clarification is requested since antigen and vaccine amounts for producing immune response are mostly in small quantities (such as micrograms and milligrams).

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*Claim Rejections - 35 U.S.C. § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 39-61 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/06921 of record.

WO discloses formulations containing monoglycerides and fatty acids in claimed amounts. The composition is for the delivery of vaccines (note pages 8-11, 17-21, 45-47 and claims).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that claims as amended overcome the rejection. This argument is not found to be persuasive since as pointed out above, the amendment, 'wherein the percentage of monoglyceride a) in fatty acid b0' is confusing and the reference still reads on instant claims. Applicant once again argues that WO discloses colloidal particles based on monoglycerides and fragmenting agents and synthetic detergents. This argument is not found to be persuasive since instant claim language does not exclude the presence of these additional components present in the prior art. Instant require the

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presence of a 'preparation which contains at least 80 % monoglyceride and a fatty acid and an antigen; the reference teaches these components.

5. Claims 39-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts (4,446,165).

Roberts discloses a composition containing monoolein and a fatty acid (note Example XII on col. 14). The examiner notes that Roberts teaches stearic acid which is a saturated fatty acid. However, instant claims recite 'may contain' which means that unsaturation is not a requirement. The reference reads on instant claims.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

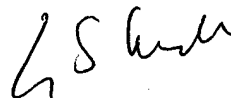
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

*gsk*

March 12, 2001